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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Aliassghar N. Tofighi et al.	Art Unit:	3732
Serial No.:	10/027,656	Examiner:	Anuradha Ramana
Filed:	December 21, 2001	Customer No.:	21559
Title:	MACHINABLE PREFORMED CALCIUM PHOSPHATE BONE SUBSTITUTE MATERIAL IMPLANTS		

Commissioner for Patents
P.O. Box 1450
Arlington, VA 22313-1450

DECLARATION OF DR. ALIASSGHAR N. TOFIGHI UNDER 37 C.F.R. § 1.132

I, ALIASSGHAR N. TOFIGHI, declare:

1. I am a named inventor of the subject matter claimed in United States Patent Application Serial No. 10/027,656 filed on December 21, 2001.

2. I have read and understood the Office Action, dated May 2, 2003, and Lee et al., U.S. Patent No. 6,117,456 (hereinafter "the '456 patent"), the reference cited by the Examiner, and, as a named inventor of the subject matter disclosed in Lee et al., I fully understand its technical content.

3. I received a Ph.D. in Material Science from the National Polytechnic Institute of Toulouse, France in 1982, specializing in the field of material science. I have over 11 years of experience in the field of calcium phosphate chemistry and bone cement biomaterials.

4. The present invention features a bone implant with high compressive strength (e.g., greater than 60 MPa) that is produced using a dense powder composed of an intimate mixture of calcium phosphate precursor materials that react under physiological conditions to form poorly crystalline hydroxyapatite *in vivo*, which is ultimately remodeled into bone (see, e.g., p. 7, lines 10-16, of the specification). As I explain in detail below, the bone implant having a compressive strength greater than 60 MPa that is described and claimed in the present application is not disclosed by the '456 patent, and adjusting the hardness or compressive strength of the poorly crystalline apatitic calcium phosphate material disclosed in the '456 patent using routine methods and ordinary skill in the art would not yield the presently claimed bone implant.

5. The methods for producing a bone implant of the present invention have been used by researchers working under the direction of both myself and the other inventors to successfully and reliably manufacture a bone implant having high compressive strength (i.e., greater than 60 MPa). As is described in the present specification, the methods involve high energy grinding of a composition composed of at least two calcium phosphate materials (e.g., for 3 hours at 100 rpm; see, e.g., Example 3, page 21, of the specification). This high energy grinding method produces a fine powder that is additionally sieved to remove large particles, i.e., those larger than 125 μm. The final result is a very fine powder of intimately mixed, solid calcium phosphate particles, in which the particles are integrated on a nanometer scale (i.e., the grinding method produces a powder of very dense, uniform particles with a tightly packed crystal structure). The powder can then be pressed into a very strong, high-density machinable implant for insertion into the body. This achievement is not possible by simply combining calcium phosphate materials to form a paste or putty, as is described in Examples 8 and 9 of the '456 patent, or by grinding the dry calcium phosphate materials, either before or after their combination, as is described in Examples 10 and 11 of the '456 patent.

Examples 10 and 11 of the '456 patent disclose grinding of the calcium phosphate materials for five or ten minutes to yield a powder with a grain size of less than, e.g., 25 μm (see, e.g., Table 3); this method does not produce the very fine powder of intimately mixed, solid calcium phosphate particles that is used to form the presently claimed bone implant with high

compressive strength. The grinding method of the '456 patent does not integrate at least two calcium phosphate materials at the nanometer level, as does the high energy grinding method disclosed in the present application. Therefore, the methods of the '456 patent do not produce a dense powder having uniform, nano-sized particles with tightly packed crystals; characteristics of a calcium phosphate powder that are required for the manufacture of a bone implant with a high compressive strength of at least about 60 MPa.

As proof that the methods of the '456 patent do not yield a bone implant with a compressive strength of at least about 60 MPa, I direct the Examiner to Example 13 of the '456 patent, which discloses that a calcium phosphate composition prepared by the method of the '456 patent has a compressive strength of 7-9 MPa, which is an order of magnitude less than a compressive strength of at least about 60 MPa recited in the present claims.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

Date: 11-03-2003

A. TOFIGHI

Aliassghar N. Tofighi, Ph.D.

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